

**AMENDMENTS TO THE DRAWINGS:**

The Office Action objected to the drawings because they contain reference characters not mentioned in the description. On Replacement Sheet 7/19 in fig. 16 the reference numeral 543 has been deleted (twice).

The Office Action objected to the drawings as failing to comply with 37 CFR 1.84(p)(4) because reference character "527" has been used to designate both latch and catch. Applicants include a replacement drawing to overcome this objection.

The Office Action objected to the drawings under 37 CFR 1.83(a) because they fail to show: "edge portion 529" as described in the specification, page 19. Applicants include a replacement drawing to overcome this objection.

Further, on Replacement Sheet 6/19 in fig. 14 the reference numeral 552 now points to the same portion of the release member 550 as in fig. 18, i.e. the vertical portion.

## REMARKS:

### Summary of Claim Amendments and Pending Claims

Upon entry of the present amendment, claims 1-32 are pending and claims 12-20, 23, and 28-32 are withdrawn. Claims 1, 3-6, 8-11, 21-22 and 24-27 are pending for examination. The pending independent claims have been amended. No new matter is added.

The originally filed specification and claims support the present amendments. By entry of the present amendment, claim 1, as well as independent claims 21, 22, 25 and 27 are amended.

Applicants reserve the right to file continuation and/or divisional applications directed to subject matter in any canceled or withdrawn claims.

### Response to Objections

The Office Action objected to the drawings because of informalities in the drawings. In response to these objections, Applicants have amended the specification and include replacement sheets for the drawings. Accordingly, Applicants respectfully request withdrawal of the objections.

### The 35 U.S.C. §102(b) Rejections

The Office Action rejected claims 1-11, 21-22, 24-27 under 35 U.S.C. §102(b) as being anticipated by Tsals et al. (US 5,858,001).

The Examiner has cited Tsals (US 5,858,001) as anticipating claims 1-11, 21-22 and 24-27.

To understand how the examiner reads claims 1 and 2 onto Tsals, applicants assume the examiner consider the device of Tsals to be operated in the following way.

1. When the drug has been infused the device is in a first state as shown e.g. in fig. 2.
2. To first withdraw the needle the user pulls the housing 11 (i.e. the release means of claim 1) upwardly to an intermediate position thereby withdrawing the needle to its retracted position (i.e. corresponding to fig. 1).
3. To second release the device from the skin the user further pulls the housing 11 which via the hinge 28 is attached to the periphery of member 13 provided with an adhesive mounting surface 14.

The examiner has identified the structure 15 as a flexible sheet member, however, 15 merely denotes a release liner which is inherently different from the adhesive flexible sheet member 570, 270 of the present invention.

To effectively remove such a flexible sheet member from a skin surface it is necessary to start pulling from the periphery, for which reason the release means (e.g. the strip member) is attached to the periphery of the sheet member and not the periphery of the device per se.

Amended claim 1 reads as follows:

1. A medical device, comprising:
  - a lower mounting surface adapted for application towards the skin of a subject,
  - a sheet member extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin,
  - a transcutaneous device adapted to penetrate the skin of the subject and being mounted for movement between an extended position in which the transcutaneous device projects relative to the lower mounting surface and a retracted position in which the transcutaneous device is retracted relative to the lower mounting surface,
  - a release attached to a peripheral portion of the sheet member, the release comprising a user gripable portion moveable relative to the lower mounting surface, the user gripable portion being operatable from a first condition through an intermediate condition to a second condition,
  - whereby operation of the user gripable portion from the first to the intermediate condition causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the user gripable portion from the intermediate to the second condition causes release of the attaching means.

To aid the Examiners understanding, applicants submit that the present invention works as follows:

1. The user actuates the user gripable portion (e.g. by pulling the strip (540, 676 or 276) from its first condition) and thereby causes the transcutaneous device to be moved from the extended position to the retracted position (corresponding to the strip's intermediate condition).
2. The user continues to actuate the user gripable portion (e.g. by pulling the strip from its intermediate position) thereby starting to peel the sheet from the skin starting at a peripheral edge thereof.

3. The user continues to actuate the user gripable portion thereby removing the sheet and thereby the device from the skin (corresponding to the strip's second condition).

Tsals thus fails to render the pending claims unpatentable because it fails to disclose the following features:

- A sheet member extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin.
- Release means attached to a peripheral portion of the sheet member, the release means comprising a user gripable portion moveable relative to the lower mounting surface.
- The release means attached to the sheet member also serving to move the transcutaneous device from the extended position to the retracted position.

Even if the device of Tsals were provided with a sheet member extending peripherally relative to the mounting surface, the housing 11 (serving as the release means) would not be attached to a peripheral portion of the sheet member. In fact, it would be very difficult to release such a device from a skin surface by merely pulling the housing 11 away from the skin surface.

Neither Tsals nor any other cited reference discloses a release or a release means serving to first move the transcutaneous device from the extended position to the retracted position, and being attached to a peripheral portion of a sheet member.

#### **The 35 U.S.C. §112(first paragraph) Rejections and Amendments to the Specification**

The Office Action rejected claim 6 under 35 U.S.C. §112(first paragraph) as failing to comply with the written description requirement.

Claim 6 defines:

A medical device as in claim 3, wherein the transcutaneous device retraction means comprises a flexible strip portion arranged below a portion of the transcutaneous device, whereby the flexible strip portion will lift the transcutaneous device from the extended position to the retracted position when the user gripable portion is operated from the first to the intermediate state.

This feature is described in the specification as follows:

In the shown embodiment the release member is in the form of a strip formed from a flexible material and having an inner and an outer end, the strip being threaded through an opening 512 in the housing, the strip thereby forming the user gripable portion 551 and the needle retraction portion 552, the inner end of the strip being attached to the housing and the outer end of the strip being attached to a peripheral portion of the sheet member 570 or, alternatively, a peripheral portion of the housing. In the projection shown in fig. 18 the release member is shown in its initial position, the retraction portion forming a loop 555 arranged below the lower arm of the needle carrier, this position allowing the lower arm to be moved to its actuated position and thereby the needle to its extended position.

When the user decides to remove the needle unit from the skin, the user grips the user gripable portion 551, lifts it away from the housing and pulls it upwardly whereby the loop shortens thereby forcing the lower arm upwardly, this position corresponding to an intermediate release state. By this action the lower arm engages the inclined edge portion 529 of the catch 527 thereby forcing it outwardly until it snaps back under the lower arm corresponding to the position shown in fig. 16. As the actuation member 540 has been removed from the needle unit, the needle carrier is irreversibly locked in its retracted position. When the user further pulls in the release member, the peripheral portion of the sheet member to which the release member is attached will be lifted off the skin, whereby the needle unit with its attached reservoir unit can be removed from the skin, this as shown and described in figs. 7-9.

### **The Double Patenting Rejections**

The Office Action provisionally rejected claims 1-11, 21-22, 24-27 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 of copending US Patent Application No. 11/326,550, claims 1-14 of US Application No. 11/407647 and claims 1-47 of US Application No. 11/411081. Applicants will file the appropriate terminal disclaimers upon allowance of the pending claims.

### **The Rejections based on means plus function language**

The specification has been amended to recite examples of the structure that performs the corresponding functions.

### **Conclusion**

In view of the above, Applicants submit that the application is now in condition for allowance and issue and respectfully requests early action to that end. Applicants believe that no additional fees are due. However, should any fees be due, the Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The undersigned invites the Examiner to contact him/her by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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